Qualitative synthesis and the development of clinical guidelines: towards a person-centred approach

by

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Abstract

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Traditionally, clinical guidelines rely on objective evidence from quantitative research, largely derived from Randomized Controlled Trials (RCTs) of specific interventions in a defined healthcare area. Findings from qualitative research tend to be under-represented or overlooked because qualitative studies are more subjective, relatively small in scale and contextually bound. They may, however, contain important information about how a particular intervention works or doesn't work as well as relevant insights concerning the experiences, values and beliefs of key stakeholders with regard to the intervention or healthcare area. In recent years some novel approaches have been developed to address the lack of qualitative data within clinical guidelines. The most popular of these approaches is 'qualitative synthesis', a method that brings together the findings from isolated qualitative studies exploring the same or similar phenomena with a view to eliciting new, more abstract findings such that the whole is greater than the sum of the parts. More recently, techniques derived from qualitative synthesis have been adapted and used to inform global guidelines in the field of maternity care. Recognition that the findings from qualitative synthesis constitute a form of 'evidence' represents a major breakthrough for qualitative research generally but the newly emerging field is a highly contested area. There are internal tensions relating to the nature of qualitative synthesis itself, including the methodological and philosophical basis of the approach, as well as wider tensions relating to the incorporation of interpretive findings into the positivist frameworks associated with clinical guidelines.

By referring to eight publications I have either authored or co-authored I will explore the qualitative synthesis landscape from its roots in the interpretive paradigm to its current application in guideline development. I will start by placing qualitative synthesis within the wider context of qualitative

research and introduce the most commonly used synthesis technique, meta-ethnography. I will go on to examine some of the methodological, terminological and philosophical tensions that continue to challenge the credibility of this approach and highlight how I have addressed some of these issues by referring to several qualitative syntheses I have published. I will explain how the findings from these syntheses have been incorporated into clinical guidelines in maternity care and highlight some of the compromises that have been made to accommodate this endeavour within the wider context of Evidence Based Medicine (EBM). I will draw on some of the writings of the German philosopher, Jürgen Habermas, and explore how Habermas' concept of *colonization* might be applied in this context to illuminate some of the areas of contestation. By developing some of Habermas' theoretical discourse I will suggest that the method of qualitative synthesis is evolving in an 'interference zone' where competing claims for integrity strive for priority. I will juxtapose this position with a more utilitarian view of qualitative research and suggest that the findings from qualitative synthesis reflect a wide range of views, beliefs and experiences and represent a collective voice that can be utilized by guideline panels and policy makers. Finally, I will draw on the work of Carl Rogers, psychotherapist and pioneer of the '*person centred care'* model, to illustrate how a patient led approach to guideline development, using qualitative-synthesis as a method, might represent a shift in global healthcare strategy towards more authentic and inclusive guidelines.

Acknowledgements

I would like to thank my PhD supervisors, Professor Soo Downe and Professor Mick McKeown for their ongoing support, guidance and advice. My journey wouldn't have been quite so stimulating without their wide-ranging socio-political insights and individual and combined passion for the subject area. I'd particularly like to thank Soo for continuing to challenge, encourage and motivate me; her unbounded energy and optimism is both a revelation and an inspiration. I'd also like to thank Dr Carol Kingdon, my Research Degrees Tutor (RDT) for her support, encouragement and lengthy 'what's app' discussions on various topics relating to this commentary. Thanks too, to colleagues at the WHO for giving me the opportunity to engage with this fascinating area of research and for continuing to support and develop my interest in this area. Many thanks to my patient partner, Jane Swarbrick, for her prompts, hugs and encouragement, particularly when doubts crept in and stress levels mounted. Her unwavering love and support for me over the last 14 months has been a source of confidence and strength for which I am eternally grateful. Finally, a huge thank you to all of the women and other stakeholders, from all corners of the world, who gave up their time to speak to a researcher, never quite knowing how far their voices would reach. I am indebted to them and humbled by them and I sincerely hope that in the course of my own journey I have represented their collective and individual voices with grace, respect and authenticity.

Table of Contents

Contents

Qualitative synthesis and the development of clinical guidelines: towards a person-centred approach

Introduction

Over the last five decades treatment decisions in a healthcare context have been informed by principles derived from Evidence Based Medicine (EBM). These principles have consistently been defined as "*the integration of clinical expertise with the best available external clinical evidence from systematic research*" (Sackett et al., 1996; Sackett, 1997; Masic et al., 2008; Djulbegovic & Guyatt, 2017). Whilst the former component of this definition is poorly described and open to interpretation the latter part can be summarized as the latest information on a particular practice or intervention, primarily using data obtained from Randomized Controlled Trials (RCT's) (Haynes et al., 2002; Wieten, 2018). The relative prominence of formal evidence over expertise in medical and clinical decision-making is reflected in 'the evidence hierarchy', a categorization of different levels of evidence in the form of a pyramid, where evidence from RCT's is placed at the top, followed by cohort studies, case-controlled studies, case series or care reports and expert opinion at the bottom (Canadian Task Force, 1979; Evans, 2003; Burns et al., 2011).

The emphasis on clinical evidence is at the heart of the EBM movement as it was established at a time when the experiential authority of the medical establishment was being called into question (Smith & Drummond, 2014) and efforts were being made to 'de-emphasize intuition and unsystematic clinical experience' (Guyatt et al., 1992). Archie Cochrane, whose name is synonymous with the EBM movement, was frustrated with the prevailing practice of 'expert based medicine' and proposed that a register of all RCTs in healthcare research should be compiled to catalogue and critically appraise the ever increasing numbers of RCT's with a view to helping practitioners and policymakers make clinical judgements using the most robust, currently available evidence (Cochrane, 1972). Cochrane was particularly scathing about the lack of evidence-based practice in

obstetrics and gynaecology, a criticism which ultimately prompted Sir Iain Chalmers to publish one of the first systematic reviews entitled 'Effective Care in Pregnancy and Childbirth' (Chalmers et al, 1989). Chalmers went on to establish the Cochrane Collaboration whose publications are now widely regarded as the ultimate source of best available evidence amongst healthcare researchers and practitioners (Jorgensen et al., 2006; Rosenbaum et al., 2008). The emergence of the systematic review as a distinct research method has gained prominence and now sits atop the pyramid of evidence in many iterations of the evidence hierarchy (Haidich, 2010; Murad et al., 2016).

One of the main applications of systematic reviews is in the development of clinical guidelines, statements that include recommendations intended to optimize patient care, informed by systematic reviews of evidence and assessments of the benefits and harms of alternative care options (Shekelle et al., 1999; Institute of Medicine, 2011). Viewed as objective and practical decision aids for policy makers and healthcare professionals by some, clinical guidelines have also been described as 'cookbook medicine' in which the adherence to formal procedures based largely on the generalizing tendency of the systematic review leaves little room for either professional experience/expertise or individual patient characteristics (Timmermans & Mauck, 2005; Knaapen, 2014).

Critics of clinical guidelines, and of the EBM principles on which they are based, frequently cite the (over) reliance on the RCT as the primary source of evidence in clinical decision-making and guideline development (Haynes, 2002; Cohen et al., 2004; Sheridan & Julian, 2016). The philosophical presumption that a reductionist/positivist approach to generating evidence is the correct one has been described as arrogant, privileged and even 'fascist' (Polychronis et al., 1996; Little, 2003; Holmes et al., 2006). Allied to these concerns is the absence of the 'patient's voice' in much of the literature pertaining to EBM which, arguably, reflects the lack of experiential evidence in typical iterations of the evidence hierarchy. Although the original definitions of EBM refer to, *"more thoughtful identification and compassionate use of individual patients' predicaments, rights, and*

preferences in making clinical decisions about their care" (Sackett, 1997. p.3) there is little or no acknowledgement of how the patient's values, beliefs and experiences could or should inform clinical decision making (Wieten, 2018).

However, at the same time as the EBM movement was gathering momentum, wider socio-political forces were shaping an alternative philosophy of healthcare advocating individualization and greater patient empowerment (Brown & Zavestoski, 2004; Mold, 2012). With an emphasis on respect for individual rights and patient autonomy the essence of this movement permeated into healthcare settings during the 1980's in the guise of 'patient centred care' (McWhinney, 1989; Mead & Bower, 2000; Ekman et al., 2011). Originally conceived in the 1960's as 'person centred care' by the psycho-therapist, Carl Rogers, the term patient-centred care was adopted by the medical establishment shortly afterwards as a response to calls for greater patient empowerment and the perceived limitations of the biomedical approach (Balint, 1969). Person or patient centred care is now considered to be a core component of high quality medical care (Royal College of General Practitioner [RCGP], 2014; World Health Oraganization [WHO], 2015a; Picker Institute, 2019) and, although the concept is not well defined, there is broad consensus that, from a provider perspective, the approach should include recognition of the patient's unique perspective; the development of a therapeutic relationship; and the ability to engage in shared decision-making (Castro et al., 2016; Hakansson Eklund et al., 2019; Langberg et al., 2019)[1].

In a clinical context, health professionals are therefore presented with two apparently opposing philosophies in which the generalizable and objective components of EBM, derived from RCT's, systematic reviews and clinical guidelines, are juxtaposed with the individual, humanistic and subjective characteristics of patient centred care (Bensing, 2000; Anjum, 2016). Whilst there is scope for potential conflict in reconciling these differences there is clear recognition that the patient's

[1] Throughout this commentary I will use the terms patient-centred, person-centred or woman-centred interchangeably to indicate a particular philosophy that emphasizes and respects the self-defined needs and values of an individual rather than those identified by a healthcare system or health professional.

perspective and their unique experience of disease or illness should be incorporated into treatment decisions (National Institute for Health and Care Excellence [NICE], 2013; 2015; Epstein & Street, 2011; WHO, 2015b; Ocloo & Matthews, 2016). However, in the more abstract context of clinical guidelines where the needs, values and experiences of patients aren't so visible there appears to be less scope to adopt a patient centred approach. Until recently, patient involvement in guideline development was limited to temporary engagement with guideline development groups, where patients or members of the public with relevant experience could offer views and opinions on pre-defined guideline topics (NICE, 2013; WHO, 2015a). Although the importance of patient representation in guideline development groups is acknowledged by healthcare researchers, clinical experts and patient representatives themselves, their role is sometimes viewed as tokenistic, one-dimensional and devoid of any real impact (Kelson, 2001; Van Wersch & Eccles, 2001; van de Bovenkamp & Trappenburg, 2009). Within the last few years methodological initiatives in qualitative research have led to the generation of novel approaches to guideline development where the patient voice is incorporated in a more pragmatic and inclusive manner.

One of these approaches, qualitative synthesis, has risen to prominence and is now being used to inform clinical practice guidelines on the international stage. (WHO, 2016, 2018a, 2018b). Qualitative synthesis has been defined as, "*the bringing together of findings on a chosen theme, the results of which should, in conceptual terms be greater than the sum of the parts*" (Campbell et al., 2003. p.672). Thus, the emphasis in qualitative synthesis is on interpretation and the development of theory within a particular setting or disease area (Jensen & Allen, 1996). By synthesizing the findings from single (primary) qualitative studies in a particular subject area, qualitative synthesis seeks to enhance the patient voice so that common themes and, just as importantly, divergent views may be accommodated (Noblit & Hare, 1988; Paterson, 2001; Sandelowski, 2012).

Whilst the synthesis of qualitative data has been heralded as a major breakthrough in the wider recognition of qualitative research it is not without controversy and there are several terminological,

philosophical and methodological issues that remain unresolved. (Thorne et al., 2004; Ring, 2011; Finfgeld-Connett, 2016). In addition, the process of incorporating the findings from qualitative synthesis (review findings) into clinical guidelines is a contested area where the adoption of techniques derived from quantitative systematic reviews are being challenged by those who dispute the application of 'inappropriate, standardized systems' in a qualitative context (Thorne, 2017a; Malterud, 2019).

In summary, the concept of 'evidence' within the EBM movement has traditionally relied on information from effectiveness reviews, reflected in the evidence hierarchy and often presented in the form of clinical guidelines. Despite socio-political movements advocating patient empowerment the patient's voice is poorly represented in the evidence hierarchy but, in practice, may be accommodated within the philosophy of patient-centred care. Until recently, patient representation in the development of clinical guidelines was limited to supplementary contributions to guideline development groups, but recent methodological advances in qualitative research have created a platform for patient voices to be acknowledged. The relatively new and rapidly evolving method of qualitative synthesis has been used to incorporate the views and experiences of patients into clinical guidelines and has pushed qualitative research into the spotlight. Although there are still some unresolved philosophical and methodological issues the method is being utilized by influential organizations and represents an opportunity for guideline developers to adopt and endorse a more patient-centred approach.

In this commentary I will present an overview of the qualitative synthesis landscape including the methodological challenges of performing a synthesis, the variety of procedures used to conduct a synthesis and how the findings from syntheses are currently utilized by guideline developers (largely within a maternity care context). I will also explore some of the current tensions between the demands for methodological rigor derived from the EBM movement and the counter requirements for ontological and epistemological integrity advocated by experienced qualitative researchers. By

referring to some of the writings of the German philosopher, Jürgen Habermas, I will illustrate how these tensions may be viewed from a more abstract, theoretical perspective. Finally, I will refer to the works of Carl Rogers to describe how some of the insights associated with the original 'person-centred' approach could be applied in this field to move beyond the current areas of contention to a place where patient voices are authentically reflected in the policy decision making process.

The Publications contributing to this commentary

Throughout this commentary I will refer to 8 published papers I have either authored or co-authored to illustrate and advance some of the lines of thought and arguments contributing to this body of work. Where I refer to these publications, I will highlight my name in the reference **in bold** (either as first or second author). In chronological order the papers are: -

1. **Finlayson, K.,** Dixon, A. (2008). Qualitative Meta-synthesis: A Guide for the Novice. *Nurse Researcher*, 5(2): 59-71
2. Downe, S., **Finlayson, K.,** Walsh, D. & Lavender, T. (2009). 'Weighing up and balancing out': a meta-synthesis of barriers to antenatal care for marginalised women in high-income countries'. *BJOG,* 116(4):518-29. doi: 10.1111/j.1471-0528.2008.02067.x.
3. **Finlayson, K.**, Downe, S. (2013). Why Do Women Not Use Antenatal Services in Low- and Middle-Income Countries? A Meta-Synthesis of Qualitative Studies. *PLOS Med,* 10(1): e1001373. doi:10.1371/journal.pmed.1001373.
4. **Finlayson, K.** (2015). Global access to antenatal care: a qualitative perspective. *Practising Midwife*, Feb 18(2): 10-12.
5. Downe, S., **Finlayson, K.,** Tuncalp, Ö., Gülmezoglu, M. (2016). What matters to women: A scoping review to identify the processes and outcomes of antenatal care provision that are important to healthy pregnant women*. BJOG*, 123(4):529-39. doi: 10.1111/1471-0528.13819

6. Downe, S., **Finlayson, K.**, Oladapo, O., Bonet, M., Gülmezoglu, A.M. (2018). What matters to women during childbirth: A systematic qualitative review. *PLOS ONE* 13(5): e0197791. https://doi.org/10.1371/journal.pone.0197791.

7. Downe, S., **Finlayson, K.**, Tunçalp, Ö., Gülmezoglu, A.M. (2019). Provision and uptake of routine antenatal services: a qualitative evidence synthesis. *Cochrane Database of Systematic Reviews* 2019, Issue 6. Art. No.: CD012392. DOI: 10.1002/14651858.CD012392.pub2.

8. **Finlayson, K.,** Crossland, N., Bonet, M., Downe, S. (2020). What matters to women in the postnatal period: A meta-synthesis of qualitative studies. *PLOS ONE* 15(4): e0231415. https://doi.org/10.1371/journal.pone.0231415

Reflexivity Statement

In accord with the ethos of qualitative research I feel it is important to acknowledge my preliminary thoughts on the subject area to give readers an insight into how my beliefs have been shaped and to highlight my current perspective on the subject matter. My personal beliefs were initially moulded by a boyhood fascination with the inner workings of the human body and an early interest in the physical sciences. This led to a degree in biochemistry followed by a sojourn into the world of Big Pharma and an introduction to clinical trials and the interpretation of trial-based evidence. My moral conviction that I was 'doing good' by bringing innovative and potentially life-changing drugs to the attention of the medical profession and, ultimately, the general public, was gradually undermined by an increasing perception that the pharmaceutical industry relied more on profit than principle. After several years a growing sense of unease prompted me to leave the industry and embark on a belated 'gap year' of travel and exploration. During this time I encountered various traditional and alternative approaches to healthcare and was particularly drawn to the Eastern concept of holism with its emphasis on the complex inter-relationships between physical, mental and emotional well-

being. By actively engaging with some of these approaches I also developed an appreciation of the quality of care and the associated qualities of care providers. These life experiences and intellectual understandings have brought me to a place where I appreciate the concept of 'balance'. Whether it be through a physical lens and the propensity of particles to return to a state of equilibrium or via a meta-physical understanding like the Eastern concepts of yin and yang, I believe that the natural order of a given system is intrinsically arranged to move towards a state of balance. In a scientific context I believe 'the system' is currently out of balance, propelled by an over-emphasis on objective 'reality' at the expense of subjective experience. In order to redress this perceived imbalance, I'm attracted to the existential, the individual, the personalized, the nuance and, ultimately the qualitative. Whilst I do recognise the benefits of objective exploration and, in this context, of using findings derived from RCT's and reviews of effectiveness (including meta-analyses) to determine whether a particular intervention or approach works or not, my appreciation of balance leaves me unconvinced about the merits of relying primarily on this kind of information to inform healthcare policy and guideline development.

The Origins of Qualitative Synthesis

Qualitative synthesis is rooted in the qualitative mode of inquiry and follows the ontological and epistemological threads inherent in qualitative research. Qualitative research *"refers to the meanings, concepts, definitions, characteristics, metaphors, symbols, and description of things and not to their counts or measures"* (Berg & Lune, 2014, p.3). In stark contrast to the assumed objectivity of quantitative research where the observed and the observer are perceived as independent of each other, qualitative research recognizes the role of the observer and their subjective experience of that which is observed (Crotty, 1998). Thus, qualitative research is interpretive and occupies a space where knowledge and meaning are constructed in a social and historical context (Guba & Lincoln, 1994). Qualitative studies are exploratory rather than definitive

and utilize techniques like interviews, focus groups and observation to examine individual perceptions of specific phenomena (Guba & Lincoln, 1994). Because of the reliance on meaning, description and experience, qualitative studies tend to involve relatively small numbers of participants and are usually framed around a setting or context. In contrast to the positivist assumptions of EBM where knowledge is primarily articulated according to numeric, generalizable principles, the value of findings from isolated, contextually bound qualitative studies may be limited and has contributed to their marginalization from the evidence hierarchy (Denzin et al., 2011).

By synthesizing the findings from different qualitative studies exploring the same or similar phenomena qualitative synthesis relinquishes the contextual, historical and isolationist ties associated with the original (primary) studies and offers 'new' findings representing the views of a wider and potentially more diverse population. According to Noblit and Hare (1988), the early pioneers of this approach, the synthesis of findings should be driven by a desire to 'construct adequate interpretive explanations' rather than aggregative summaries. They draw on Strike and Posner's (1983) definition of synthesis in which separate parts are brought together to form a 'whole' and emphasise the importance of interpretation such that the constructed whole is somehow greater than the sum of its constituent parts (Noblit & Hare, 1988).

The Development of Qualitative Synthesis

Noblit and Hare's original synthesis of qualitative findings was conducted in the field of education and utilized a seven-step process (see box 1) which they termed 'meta-ethnography'. This is by far the most popular method of synthesis and, although I will refer to other methods of synthesis throughout this commentary, much of the narrative will focus on this technique because of its popularity and my own familiarity with it.

Box 1. Seven steps of meta-ethnography (Noblit & Hare, 1988)

1. **Getting started** - identifying an intellectual interest that qualitative research might inform
2. **Deciding what is relevant to the initial interest** – purposeful selection of relevant studies
3. **Reading the studies** – repeated reading of the studies and noting of interpretive metaphors
4. **Determining how the studies are related** - creating a list of the key metaphors, phrases, ideas, and/ or concepts (and their relations) used in each study.
5. **Translating the studies into one another** – translating the key metaphors and concepts from each study into one another in a reciprocal (when concepts are similar) or refutational (where concepts are different) manner.
6. **Synthesising translations** – comparing the translations from step 5 in a second level of synthesis to identify common or overarching concepts and to develop new interpretations from these.
7. **Expressing the synthesis** – communicating the synthesis to an audience in a suitable format.

Although their original synthesis included only ethnographic studies, they indicated that meta-ethnography could be used to synthesize qualitative studies with different methodological approaches, e.g. phenomenology, grounded theory, etc; (Noblit & Hare, 1988). They also called for the development of more synthesis techniques and over the following decades a proliferation of different methods evolved (Lee et al., 2015). Largely because of the range of different approaches to synthesis, as well as the assortment of terms used to describe the same or similar procedures, the area is highly contested and there is currently no consensus about the 'best' method or an agreed way forward. These areas of contestation are highlighted in the first of my papers contributing to this synoptic commentary (**Finlayson** & Dixon, 2008). This paper was the first to summarize the different approaches to qualitative synthesis from the perspective of an early career researcher and includes a set of reflective guidelines for consideration by researchers new to the field. At this time the issues revolved around three main areas, (i) the terminology used to describe the synthesis of

qualitative data; (ii) the philosophical assumptions of the method and (iii) the methodological components of the technique; and it is telling that these same issues remain topics of debate more than 10 years later.

Terminological issues

The terms 'qualitative synthesis' or 'qualitative meta-synthesis' tend to be used as overarching descriptors to indicate a general methodological approach (Thorne et al., 2004; Ring et al., 2011). The suffix 'meta' not only denotes an alignment with the quantitative equivalent, meta-analysis, it also reflects an important characteristic since 'meta', from the Greek meaning 'above' or 'beyond' acknowledges the interpretive nature of qualitative synthesis. There is an argument that the term 'meta' should not be used as a precursor to the word synthesis unless there is evidence of some level of interpretation of data (rather than aggregation) (Thorne, 2017b; Britten et al., 2017). Other terms used to describe the synthesis of qualitative data tend to reflect the level of interpretation and range from more aggregative methods like meta-summary (Sandelowski & Barosso 2003) and meta-aggregation (Lockwood et al., 2015), through to more descriptive approaches like thematic synthesis (Thomas & Harden, 2008) and, finally, interpretive methods like grounded formal theory (Kearney, 1998) and meta-ethnography (Noblit & Hare, 1988). As noted above, the term 'meta-ethnography' has been used to describe the synthesis of findings from qualitative studies according to the method developed by Noblit and Hare (1988). A number of authors use this term in the title of their publications to denote an adherence to this particular methodological approach (see for example, Campbell et al., 2003; Atkins et al., 2008; Toye et al., 2017).

A variation of the broad descriptor for the synthesis of qualitative data is advocated by The Cochrane Qualitative and Implementation Methods Group (CQIMG) who use the term 'Qualitative Evidence Synthesis (QES)' to emphasize the evidence generating capacity of the technique. They also support a more systematic approach to the process, outlined in a series of six papers published in 2018, but

don't endorse a specific synthesis technique (Noyes et al., 2018a[2]). Thematic synthesis (Thomas & Harden, 2008), framework synthesis (Carroll, 2011) and meta-ethnography (Noblit & Hare, 1988) are all highlighted by CQIMG but they suggest a variety of factors should be considered (e.g. the research question, epistemology, resources, expertise and purpose of the review) before a particular method is adopted (Booth et al., 2016; Noyes et al., 2018b).

In this commentary I will use the term 'qualitative synthesis' to refer to the range of synthesis techniques (outlined above) unless I am referring to a specific method where I will use the term associated with the method.

Philosophical issues

Since qualitative studies are culturally, contextually and historically bound it may be difficult to synthesize findings without undermining their epistemological integrity (Sandelowski et al., 1997). The legitimacy of combining the views and experiences of a particular phenomenon by merging the voices of diverse populations in different settings at distinct time periods is debateable. However, this view may be countered by arguments that the synthesis of individual belief systems, values and forms of self-expression already exists in the original (primary) studies contributing to a qualitative synthesis (Sandelowski & Barroso, 2002; Zimmer, 2006).

Another issue that attracts academic attention is the validity of synthesizing findings from studies using disparate qualitative methodologies. Although qualitative methodologies like ethnography, grounded theory and phenomenology share the same epistemological roots and similar theoretical perspectives, they utilize different methods. For example, phenomenology relies on in-depth interviews with a select number of individuals to explore their 'lifeworld' experience, while ethnography relies on researcher observation and interviews with multiple informants to explore the relationship between culture and behaviour (Berg & Lune, 2014). In practical terms, the question then becomes one of whether a synthesis of, for example, 'women's experiences of breastfeeding',

[2] This is a reference to the first of the six papers and provides an introduction and overview to the series.

can accommodate a phenomenological study of five breastfeeding mothers in a UK city and an ethnographic study exploring the child-rearing practices of a nomadic Arabic community, in which breastfeeding may form a part. According to Zimmer (2006) any attempts to synthesize the data from such distinct methodologies would represent a 'violent transgression' and undermine the epistemology on which they are based (p.314). Whilst there is credence in the integrity of this view there is also a more expansive argument pertaining to the purpose of qualitative research. Noblit and Hare (1988), suggest that "*utilitarian culture places unique demands on qualitative research to be practical*" (p.11). In other words, society expects qualitative research to be useful, rather than isolated and repeated academic explorations of the same or similar phenomena utilizing different qualitative methodologies. This view, and one which I share, is echoed by other leading qualitative researchers who suggest that qualitative research risks being marginalized from policy, strategy and practice if it is not presented in a format that offers plausible utility (Silverman, 1997; Finfgeld, 2003; Sandelowski, 2004; Morse, 2012; Lockwood et al., 2015).

Methodological issues

Arguably, the topic that generates most controversy amongst researchers working in this field is the degree of methodological rigor applied to the synthesis of qualitative data. The contestation largely stems from calls for robust, objective and systematic protocols advocated by academics and organizations more familiar with applying quantitative methodologies to data synthesis and competing claims for preserving the inherent theoretical and epistemological nature of qualitative study by academics with considerable experience in qualitative research (Finfgeld-Connett, 2016; Thorne, 2017a; Malterud, 2019). According to advocates of the former position the methodological approach to qualitative synthesis should address most, if not all, of the strict parameters currently applied to systematic reviews of quantitative data (meta-analysis). The CQIMG recommend adherence to several sets of standards including :-

- PRISMA (Preferred Reporting Items for Systematic reviews and Meta-analysis)

- ENTREQ guidelines (Enhancing transparency in reporting the synthesis of qualitative research)
- STARLITE guidelines (Sampling strategy, Type of study, Approaches, Range of years, Limits, Inclusion and exclusions, Terms used, Electronic sources)
- CASP (Critical Appraisal Skills Programme) to assess the quality of included studies
- GRADE CERQual (Confidence in the Evidence from Reviews of Qualitative research) to evaluate the level of confidence in the review findings

(Flemming et al, 2018; Harris et al., 2018; Noyes et al., 2018b).

The meta-ethnographic approach to synthesis, has also been subject to contemporary evaluation in the form of the eMERGe guidance on reporting standards whereby researchers conducting meta-ethnographies are advised to adhere to 19 different reporting standards (France et al., 2019).

According to some experienced qualitative researcher's the increasing drive towards standardized approaches places too much emphasis on technique and not enough on the interpretive essence of the method (Finfgeld-Connett, 2016; Thorne, 2017a; Malterud, 2019; Bergdhal 2019). There is increasing concern that syntheses adopting these 'new standards' undermine the original ethos of qualitative synthesis and should be considered as a separate pursuit,

"*Among the problematic assumptions that seem to have been driving this newer species of meta-synthesis products are the mistaken notions that rigor is merely a matter of a clearly defined methodology, that reporting standards can serve as a proxy for quality criteria, and that textual "sound bites" reflective of themes found with some frequency across a data set can effectively serve as a reasonable representation for a complex and dynamic conceptualization*" (Thorne, 2017a, p.5).

Qualitative synthesis, as perceived by Thorne, is interpretive in nature, inductively derived and contributes meaningfully to the understanding of an important phenomenon, rather than an aggregative thematic summary of previously published reports (Thorne, 2017b).

Where there seems to be some level of agreement between these two positions is that the quality of syntheses published in recent years is poor (Thorne, 2017a, Britten et al., 2017). In a systematic review of meta-ethnographies published in healthcare research during the period 2012-2013 France et al. (2014) identified 32 papers, 66% of which did not follow the principles of meta-ethnography and 38% did not report any new interpretation of the data. Findings such as this suggest that the Cochrane drive to improve standards is valid and Thorne's view regarding the lack of interpretation in recent manifestations of meta-synthesis is also compelling.

In summary, the synthesis of qualitative data is an evolving and contested area with unresolved issues pertaining to the terminological, philosophical and methodological characteristics of the approach. However, if one accepts that the synthesis of qualitative data is a valid technique with the aspiration to give voice to the views and experiences of those it seeks to represent then it's utility in generating new theory and insights with potential application in policy and practice is a worthy endeavour.

In the next stage of this synoptic commentary I will highlight the purpose of qualitative synthesis and explore some of the inherent challenges in conducting a synthesis in this rapidly evolving field.

The Purpose of Qualitative Synthesis

Noblit and Hare (1988) indicate that the purpose of qualitative synthesis is the generation of new knowledge and suggest that it might be appreciated by academics, policy researchers and policy makers "*who wish to use humanistic research in their deliberations but who are at a loss about how to 'reduce' it"* (p.11). More specifically, Flemming et al. (2019) suggest that qualitative synthesis can be used to explore:-

- Health-related behaviours or experiences of illness.
- Why and how a policy or intervention works.

- Appropriateness or acceptability of interventions.
- Barriers and facilitators to implementation of interventions.
- Gaps in primary qualitative research evidence, e.g. gaps about knowledge of the acceptability of intervention.

More recent applications of meta-ethnography highlight it's use as a vehicle for developing novel concepts or theoretical advances (Britten et al., 2002; Finfgeld-Connett, 2016; Toye et al., 2017; Cahill et al., 2018;). This was our intention in the two studies exploring access to antenatal care amongst women from different geographical contexts (Downe, **Finlayson,** et al., 2009; **Finlayson &** Downe, 2013). In the first of these studies we wanted to find out why 'marginalized' women (e.g. refugees, asylum seekers, ethnic minorities, travelling communities, etc;) didn't attend antenatal care in high-income countries and used an adaptation of the health belief model (Bluestein & Ruteledge, 1993) to illustrate the findings (Downe, **Finlayson,** et al., 2009). This was in response to a commissioned piece of work by CEMACH (The Confidential Enquiry into Maternal and Child Health) to better understand why a disproportionate number of women from marginalized communities were dying during the antenatal period. In the second, related, study we wanted to explore the reasons behind poor engagement with antenatal care providers in low and middle-income countries (LMICs) where global rates of maternal mortality are disproportionately high. Using the findings from the meta-ethnography we developed a hypothetical model illustrating a dissonance between the theories and principles of standard antenatal care programmes and the beliefs, attitudes and experiences of the women included in our synthesis (**Finlayson** & Downe, 2013). The relevance of this model was summarized in a follow-up opinion article highlighting the importance of context specific data (derived from qualitative studies) in the development of successful implementation strategies (**Finlayson**, 2015). Findings from the original meta-ethnography came to the attention of a scientific officer at The World Health Organization (WHO) who contacted us to discuss our methods and theory. These conversations ultimately led to our involvement in the development of the WHO

Guidelines on Antenatal Care, the first set of maternity care guidelines to incorporate findings from a synthesis of qualitative studies (WHO, 2016).

Conducting a Qualitative Synthesis

As discussed previously, a wide range of methods have been used to conduct syntheses of qualitative studies ranging from aggregative approaches more resonant with the positivist paradigm to methods more clearly aligned with interpretive perspectives. Regardless of the merits of each method the choice of which one to use is challenging as the whole area is still relatively new and in a state of flux. In our 'guide to meta-synthesis for the novice' **(Finlayson** & Dixon, 2008**)** we postulated that if the aim of the synthesis was exploratory and theory driven then a more interpretive, inductive approach like meta-ethnography might be appropriate, whereas, if the purpose was of a more practical nature, i.e. to inform a policy decision or a clinical guideline, then a more descriptive or aggregative method might be more suitable. With hindsight this seems rather simplistic, and although I still agree with the sentiment, more recent publications highlight a range of factors that might be considered before a particular method is chosen (Barnett-Page & Thomas, 2009; Booth, et al., 2016, Flemming, et al., 2019). These include the nature of the question being addressed, the amount of time and resources available, the level of expertise required, the type of data and number of studies, the intended audience (e.g. academics, policymakers, practitioners) and the reviewers familiarity with a particular method (Booth et al, 2016). Some of the key issues are outlined below:-

The Research Question

According to Noblit and Hare (1988), initial interest in a particular topic may lead to the construction of a research question though this doesn't need to be finalized 'a priori' and may be "*modified, specified, or elaborated as one discovers new accounts*" (Nobilt & Hare, 1988, p.26). This degree of iteration may be uncomfortable to researchers coming from a more positivist stance where the framing of a research question tends to adhere to a particular structure, for example, the PICO

(Population, Intervention, Comparison, Outcome) formula, often used in quantitative studies and meta-analyses (Ring et al., 2010). Adaptations of the PICO structure have been proposed for qualitative syntheses including SPIDER (Sample, Phenomenon of Interest, Design, Evaluation, Research type) (Cooke et al., 2012) and PEO (Population, Exposure, Outcome) (Khan et al., 2003) both of which may be useful to clarify a research question. We have adopted both approaches (iterative and fixed) in our syntheses and, although the PEO structure offers a degree of clarity that helps to inform the search strategy, the flexibility of a more iterative approach creates more room for a qualitative synthesis to develop. In our qualitative meta-synthesis exploring access to antenatal care amongst marginalized women in HICs **(**Downe, **Finlayson** et al., 2009) we adopted Noblit and Hare's (1988) iterative approach. This proved useful as we originally set out to explore access to antenatal care in a UK context, but after finding only one study we expanded our research question to include studies from High-Income Countries (HICs) with similar socio-demographic profiles and antenatal care models.

Search Strategy

When searching for studies to include in a synthesis Noblit and Hare (1988) offer no clear guidance, largely because the vast array of research databases and advanced systems for retrieving data were not fully developed in the late 1980's. For meta-ethnography this has left something of a void which has gradually been filled by different researchers from a variety of disciplines entering the field over the last 30 years. As alluded to on page 14 some of the rigid, standardized, approaches to searching emanating from positivist disciplines like epidemiology and information technology have clashed with methods derived from interpretivist disciplines like sociology and anthropology. The complex and exhaustive search strategies advocated by CQIMG and others (Wong et al., 2004; Booth, 2016; Harris et al., 2018) are designed to generate the maximum number of 'hits' and eliminate selection bias. However, this process, in itself, represents a more aggregative approach to knowledge generation, the inference being that by maximizing the number of studies included in a qualitative synthesis the findings somehow become more 'valid' (Finfgeld-Connett, 2016; Thorne, 2017a;

Malterud, 2019). Several authors suggest that strategies more aligned with qualitative methodologies may be more appropriate, e.g. using data saturation or theoretical saturation to guide the search strategy(Sandelowski et al., 1997; Dixon-Woods et al., 2006; Downe, 2008) , and, in the interests of maintaining coherence and integrity, this is an approach that I feel more comfortable with.

In practical terms, the number of papers included in a qualitative synthesis can depend on the scope of the topic and the framing of the question. Larger numbers of studies may require more resources, more time and more complicated data-extraction, analysis and synthesis techniques. For example, a meta-study exploring patient's experiences of chronic illness included 292 studies and required a committed team of experienced researchers working long hours over several years to complete the study (Paterson, 2001b; Thorne et al., 2002). Sandelowski et al. (1997) highlight the wealth of information contained in each study and suggest that more than 10 studies in a qualitative synthesis curtails extensive analysis and threatens the interpretive validity of the findings. Our meta-synthesis of antenatal care access amongst marginalized women in HICs included only 8 studies and, arguably, this relatively small number was determined by the narrow parameters of our research question (Downe, **Finlayson** et al., 2009). In our qualitative evidence synthesis (QES) of antenatal provision and access amongst women and healthcare providers, we included 85 papers, primarily because the scope of the question was more expansive and the searches more exhaustive (Downe, **Finlayson** et al., 2019). Arguably, we could have produced an equally valid piece of research by employing data saturation techniques to limit the number of primary papers, but we were guided by a Cochrane endorsed QES protocol and felt it was important to adhere to the methodological approach.

Critical Appraisal

Arguments persist about the validity of using appraisal instruments to assess study quality in a qualitative synthesis (see for example, Carroll & Booth, 2014; Sandelowski, 2014). Attempts to standardize this aspect of qualitative synthesis, drawing on positivist demands for methodological

rigor, may inadvertently lead to bias by prioritizing technique over content (Majid & Vanstone, 2019). Thorne (2017a) argues that excluding studies on the basis of methodological technique alone jeopardizes the integrity of the synthesis,

"the reader has no capacity to judge what gorgeous but imperfect interpretations may have been excluded, and what technically correct but 'bloodless' and unimaginative findings may have been privileged in delineating the final meta-synthesis sample" (p.7).

Interestingly, the recent eMERGe guidelines outlining reporting standards for meta-ethnographies make no mention of critical appraisal (France et al., 2019) in accord with Noblit and Hare's (1988) original text where this subject remains unexplored. In contrast to these views most authors working in the field acknowledge that some form of evaluation should be employed, whether it be via informal discussions amongst review authors or a comprehensive assessment of numerous study criteria like the 38 item Evaluation Tool for Qualitative Studies (ETQS) (Long & Godfrey, 2004). The use of quality appraisal tools is increasing and in a recent review of qualitative syntheses published over a four-year period, Hannes and Macaitis (2012) found that 72% of 82 papers included one of 24 different assessment tools. This compares to a similar review conducted in 2007 which found that only 40% of 42 papers utilized a critical appraisal tool (Dixon-Woods et al., 2007). Hannes and Macaitis (2012) also established that the most commonly used tool was CASP (Critical Appraisal Skills Programme), a 10-item tool largely framed around methodological strengths and limitations.

In all of the syntheses contributing to this commentary (Downe, **Finlayson** et al., 2009, **Finlayson** & Downe, 2013; Downe, **Finlayson** et al., 2016; Downe, **Finlayson** et al; 2018; Downe, **Finlayson** et al., 2019; **Finlayson** et al., 2020) we used a tool based on an amalgamation of several different quality appraisal tools (including CASP) assessing the study scope and purpose, design, sampling strategy, analysis, interpretation, researcher reflexivity, ethical dimensions, relevance, and transferability (Walsh & Downe, 2006). The tool also incorporates an A-D scoring system addressing the credibility, transferability, dependability, and confirmability of each study and studies scoring D, according to

these criteria, are excluded. Although some studies were excluded in our meta-ethnography exploring access to antenatal care in LMICs (**Finlayson** & Downe 2013) we took a lenient approach to grading in all 3 papers, particularly with studies from LMICs where reporting standards vary and strict adherence to methodological procedures may be compromised by inexperienced but otherwise competent researchers. In this regard I agree with a reflexive statement highlighted in a review of meta-ethnography (Toye et al., 2014) which reads,

"The process I found most difficult to develop a clear view on was the process of critical appraisal. I am still not sure of the value of this although I feel that some sort of quality appraisal is important. . . I would I think still feel uncomfortable including studies that have significant methodological limitations, but feel it is difficult to make a judgment as to where the line should be drawn" (reflexive statement, p.6-7).

In summary, the methods used to conduct a qualitative synthesis remain in a state of transition and there is still a tension between positivist calls for equivalence with techniques derived from meta-analysis and interpretivist demands for epistemological integrity. As the body of literature in this field continues to grow the protagonists from both sides of these arguments continue to appeal for more transparency about how qualitative syntheses should be conducted and reported. The drive to be explicit about the methods used is, first and foremost, a call for clarity, to ensure that, on the one hand, qualitative synthesis becomes an acceptable vehicle for the generation of 'credible evidence' and, on the other, a reputable pursuit firmly rooted in the principles of qualitative research. In recent years synthesis methods have been adopted and adapted by organizations more aligned with the prevailing biomedical model to supplement and contextualize evidence from effectiveness reviews with a view to informing clinical guidelines and policy recommendations. If, as Noblit and Hare (1988) suggest, the findings from qualitative research are to be used by policy makers they need to be presented in an understandable and recognizable format which may require a degree of compromise.

In the next stage of this synoptic commentary I will explore how the patient voice is represented in clinical guidelines and discuss how the findings from qualitative syntheses may be incorporated into guideline recommendations.

Clinical Guidelines and Patient Involvement

Clinical guidelines emerged out of the EBM movement at a time when health professionals were faced with the competing demands of trying to keep up to date with the proliferation of new research and increasing pressures on their time (Timmermans & Berg, 2003; Boudoulas et al., 2015). By presenting a brief synopsis of intervention-based evidence from effectiveness reviews, usually based on data from RCT's, alongside comparator data and information on cost effectiveness, clinical guidelines provide an overview of the latest evidence in a summarized format (Schekelle et al., 2012). The regular publication of specific statements, including recommendations intended to optimize patient care, are designed to help healthcare providers and policy makers make rapid, well-informed decisions based on the best available evidence (Kredo et al., 2016). The use of such guidelines is advocated by state funded organizations like the National Health Service (NHS); regulatory bodies, (e.g. the various Royal Colleges in the UK); national standards agencies (e.g. The National Institute of Health and Care Excellence [NICE]); and global health agencies like the World Health Organization (WHO) and topic specific guidelines are regularly published and updated by these institutions (Pilling, 2008).

Despite institutional endorsement and an ever-increasing presence in healthcare settings, clinical guidelines have been the subject of critical discussion. In addition to the criticism levelled at the EBM principles on which they are based, largely revolving around the limitations of evidence derived from RCT's (see for example, Bondemark & Ruf, 2015; Boudoulas et al., 2015; Sheridan & Julian, 2016), clinical guidelines also arouse the suspicion of some healthcare professionals because of their potential to be used in a medico-legal context (Samanta et al., 2003), as a tool for over-diagnosis

(Treadwell & McCartney, 2016), or as a medium for standardization (Timmermans & Berg, 2003; Knaapen, 2015). The prescriptive nature of guidelines and the associated notion that there are 'standard patients' has led to claims that clinical guidelines undermine clinical expertise and overlook individual patient characteristics or contextual nuances, "*Thus guidelines are directed at populations with a specific disease and not at the individual patient*" (Boudoulas et al., 2015, p.195). In addition, some authors highlight the over-reliance on evidence from effectiveness reviews in clinical guidelines and the corresponding lack of emphasis given to the values, beliefs and experiences of patients and service users contributing to guidelines (Timmermans & Almeling, 2009; Gould, 2010). Such views are countered by claims that clinical guidelines should be interpreted as guidance, as opposed to rules or requirements, and that guideline recommendations should be adapted according to individual circumstances (Pilling, 2008; NICE, 2012). Furthermore, national and international organizations responsible for guideline development highlight the role of patients and/or service users as fundamental to the development of clinical guidelines (Boivin et al., 2010; NICE, 2013; WHO, 2015a).

The increasing involvement of patients and service users in guideline development is recognized as a way of ensuring advocacy, respecting the rights of citizens in health policy development and, ultimately, giving credence to the perception that patients are experts in their own right (Boivin et al., 2010). Over the last two decades NICE has consistently displayed a commitment to working with patients, service users and service user groups, initially via the establishment of an integrated Patient Involvement Unit (PIU) and, more recently, via policy initiatives aimed at maximising patient engagement (Culyer, 2005; NICE 2013). These initiatives include opportunities for multiple stakeholder groups and members of the public to comment on draft guidelines, opportunities for children and young people to become involved in healthcare decisions that may affect them as well as infrastructure and resources to enhance public engagement with guideline development (NICE, 2013).

Although these approaches appear to be supported by professional bodies and organizations like NICE and the WHO whose 'guidelines for the development of clinical guidelines' fully endorse patient representation on GDGs (WHO, 2012; NICE, 2013), there is also a perception that these types of engagement are ineffective and insufficient (van Bovenkamp & Zuiderent-Jerak, 2013; Armstrong & Bloom, 2017). Active participation may be inhibited by a lack of technical knowledge or the personal capacity to challenge professional experts (Tong et al., 2011; Ocloo & Matthews, 2016), and even if participants are perceived to be confident and technically competent, they may be criticized as being unrepresentative of the patient population (van Wersch & Eccles, 2001; van Bovenkamp & Zuiderent-Jerak, 2013). From an organizational perspective the additional resources and investment required to facilitate effective patient engagement in GDGs may not be prioritized (Brett et al., 2014) and existing hierarchical structures may limit patient ability to shape strategic or political agendas (Ocloo & Matthews, 2016). Arguably, the most significant issue relates to under-representation, whereby the vast array of views and experiences from diverse populations cannot reasonably be conveyed by individual patient representation on GDGs (Lewin et al., 2018). To address these concerns, and particularly the issue of under-representation, various authors suggest that, in addition to patient engagement in GDGs, guideline developers should utilize the findings from qualitative syntheses to inform patient related guideline parameters (Gould 2010; Langlois et al., 2018; Lewin & Glenton, 2018; Roddis et al., 2019).

Using qualitative synthesis in guideline development

There is growing recognition that guidelines sometimes fail to reflect the values, preferences, experiences and priorities of key stakeholders and that issues related to the acceptability and feasibility of interventions are not always addressed through systematic reviews of effectiveness (WHO, 2014; Langlois et al., 2018). The findings from qualitative syntheses can be used to address these shortcomings and, in recent years, an increasing body of literature has illustrated how this can be achieved (Lewin & Glenton, 2018; Flemming, et al., 2019, Downe, et al., 2019; Lewin, et al., 2019). As discussed previously, the synthesis of qualitative data is a contested area and, by extension, the

application of findings from a qualitative synthesis within the RCT dominated arena of clinical guidelines is equally challenging (Malterud, 2019). In order to penetrate the prevailing hierarchy a degree of compromise may be required and, with regard to qualitative synthesis, the utilization of certain procedures and techniques adopted or adapted from the dominant biomedical model (Wong, 2016, Malterud, 2019). In addition to the established standards derived from systematic reviews of effectiveness relating to search strategies, quality appraisal and reporting standards (including PRISMA, CASP, ENTREQ and STARLITE) recent applications of qualitative synthesis in guideline development also utilize a recently adapted tool (GRADE CERQual) to assess 'confidence' in the review findings (Lewin et al., 2015).

GRADE CERQual (Confidence in the Evidence from Reviews of Qualitative Research)

GRADE CERQual is still in development but is an adaptation of the GRADE approach (Grading of Recommendations Assessment, Development and Evaluation) used in meta-analyses to assess estimates of effect for various outcomes by evaluating the risk of bias, indirectness, inconsistency, imprecision, and publication bias. In GRADE CERQual or 'CERQual' four of these five criteria have been adapted to reflect qualitative concepts and include *Methodological Limitations in study design* (risk of bias); *Relevance* (indirectness); *Coherence* (inconsistency) and *Adequacy of data* (imprecision) (Lewin et al., 2015). In a qualitative synthesis the four components of CERQual are applied to each synthesis finding (termed a review finding) and an overall assessment is made (high, moderate, low or very low) to give an indication of the confidence in the review finding. For example, in our 'provision and uptake of antenatal care paper' (Downe, **Finlayson** et al., 2019) one of the review findings highlighted how long waiting times at health clinics discouraged women from attending. Following CERQual assessment the finding was graded as '*moderate*' because of concerns relating to the methodological limitations of some of the studies contributing to the review finding as well as the finding being largely limited to LMICs (coherence). To aid decision making, narrative review findings from qualitative syntheses (along with relevant CERQual gradings) are presented to

members of guideline committees in Evidence to Decision frameworks (EtD) (Alonso-Coello et al., 2016; Neumann et al., 2015).

Evidence to Decision Frameworks

EtDs are designed to make decision-making more systematic and transparent and include criteria to assess the effectiveness of a particular intervention (derived from meta-analyses) as well as criteria to evaluate the acceptability and feasibility of the intervention (derived from qualitative synthesis). [An example of all the EtD criteria are shown in Table 1 below].

Table 1. EtD criteria and associated sources of evidence

EtD Criteria	Explanation	Source of Evidence
Benefits and Harms	How large are the anticipated benefits of the intervention? vs How large are the anticipated harms of the intervention?	Systematic reviews of effectiveness
Certainty of evidence	What is the certainty of the evidence for benefits and harms?	Systematic reviews of effectiveness
Values	How do people value the main outcomes associated with the intervention?	Qualitative synthesis of stakeholder views on outcomes associated with intervention
Resources	How much would it cost to implement the intervention?	Systematic reviews of cost-effectiveness studies
Equity	What would be the impact of the intervention on gender, health equity and human rights?	Systematic reviews of effectiveness. Studies focusing specifically on gender, health equity and human rights in relation to the health issue or intervention
Acceptability	Is the intervention acceptable to key stakeholders?	Qualitative synthesis of stakeholder views on the health issue or intervention

Feasibility	Is the intervention feasible to implement?	Qualitative synthesis of stakeholder views on the health issue or intervention

By way of example, in the 'WHO recommendations on antenatal care for a positive pregnancy experience', (WHO, 2016) one of the interventions under investigation was a model of care known as 'midwife-led continuity-of-care' (in which a known midwife or small group of known midwives supports a woman throughout the antenatal, intrapartum and postnatal continuum). In the EtD framework addressing this question the data from effectiveness reviews suggested the intervention had a positive effect on key maternal and neonatal outcomes. This was reinforced by findings from our qualitative synthesis (Downe & **Finlayson,** 2019) which showed that the intervention was feasible to implement (in settings with well-functioning midwifery programmes) and acceptable to key stakeholders (especially women). An excerpt from the acceptability criteria, along with relevant CERQual gradings is shown below,

"*Qualitative evidence synthesized from a wide variety of settings and contexts indicates that women welcome the opportunity to build supportive, caring relationships with a midwife or a small number of midwives during the maternity phase (high confidence in the evidence) and appreciate a consistent, unhurried, woman-centred approach during ANC visits (high confidence in the evidence)"* (WHO, 2016, p.90).

In addition to the acceptability and feasibility criteria the review findings from qualitative syntheses are also being used to populate the 'values' section of the EtD framework. In this context, values refers to how stakeholders (patients or service users) value the outcomes associated with the intervention. Up until relatively recently, the outcomes associated with maternity care guidelines were clinically focused and tended to be associated with maternal and neonatal mortality & morbidity. However, as a consequence of our synthesis exploring 'what matters to women during the antenatal phase' (Downe, **Finlayson** et al., 2016) the concept of a 'positive pregnancy

experience' was developed as a key outcome of importance to women and featured in all of the EtD frameworks contributing to the WHO antenatal care guidelines (WHO, 2016) [see box 2 for the components of a positive pregnancy experience].

Box 2 – A positive pregnancy experience (Downe, **Finlayson** et al., 2016)

A positive pregnancy experience emerged as a composite outcome from our qualitative synthesis. This was informed by four sub-themes or components that mattered to women in pregnancy, across countries, cultural groups and varying socio-demographics, namely: maintaining physical and sociocultural normality; maintaining a healthy pregnancy for mother and baby (including preventing and treating risks, illness and death); effective transition to positive labour and birth; and achieving positive motherhood (including maternal self-esteem, competence, autonomy).

Ultimately, 'a positive pregnancy experience' became the 'headline' for the guidelines and was alluded to in the foreword section written by the Secretary General of the United Nations, Ban Ki-moon, who stated:-

"I welcome these guidelines, which aim to put women at the centre of care, enhancing their experience of pregnancy and ensuring that babies have the best possible start in life" (WHO, 2016, p.iv).

Furthermore, the concept of a 'positive experience' was also identified in our subsequent syntheses exploring what matters to women during labour and birth (Downe, **Finlayson** et al, 2018) and what matters to women during the post-natal period (**Finlayson,** Crossland, et al, 2020) and became the headline for the 'WHO recommendations on intrapartum care for a positive childbirth experience' (WHO, 2018a). This break from convention, emphasising the voices of women via the findings from

qualitative research, represents a major shift in direction by the WHO, a point highlighted on the first page of the intrapartum guideline:-

"It (the guideline) elevates the concept of experience of care as a critical aspect of ensuring high-quality labour and childbirth care and improved woman-centred outcomes, and not just complementary to provision of routine clinical practices" (WHO, 2018a, p.1).

Whilst the acknowledgement of the patient voice in the biomedically infused arena of clinical guidelines is to be welcomed there are lingering reservations about how this has been achieved (Thorne, 2017b, Malterud, 2019). In order to 'fit into' the pre-determined procedures and frameworks associated with guideline development, the findings from qualitative syntheses tend to be expressed in rather descriptive, aggregative terms to align with the requirements of the EtD framework (see acceptability example on p.27). The lack of interpretation and metaphorical illumination is somewhat at odds with the epistemological roots of qualitative inquiry and the "bloodless" nature of the descriptive review findings undermine the credibility of the method (Thorne, 2017a, Bergdahl, 2019a; Bergdahl, 2019b). Furthermore, important findings that don't reflect issues pertaining to values, acceptability or feasibility may be overlooked and findings graded as 'low' or 'very low' may be devalued (Lewin et al, 2015). According to Malterud (2019) the application of techniques adapted from EBM, like GRADE-CERQual, reflect crucial misunderstandings. He highlights the coherence component of GRADE-CERQual as a case in point and suggests that, whilst coherence may indicate a desired level of homogeneity in meta-analysis, the tendency towards generalization may be anathema from a qualitative perspective. He goes on to suggest that, *"rather than disturbing rigor, data incoherence may actually contribute to exciting analysis leading to new knowledge"* (Malterud, 2019, p.12). These concerns have not gone unnoticed and there are reservations from the core CERQual team about whether CERQual can even be applied to the more interpretive, metaphorical findings associated with meta-ethnography (Lewin et al., 2018).

In summary, the findings from qualitative synthesis are being used in clinical guidelines to address key patient (or service user) related issues pertaining to the acceptability and feasibility of an intervention and, significantly, highlight patient-centred outcomes that are of value to the population under investigation. Whilst these ground-breaking developments signify a major step forward for qualitative research in general and for the representation of the patient voice in the wider context of EBM, there are some enduring methodological and epistemological tensions that remain unresolved.

In the next section of this commentary I will attempt to deepen current understandings of these persistent tensions by referring to the writings of the critical theorist, Jürgen Habermas. I will draw on Habermas' theorising of 'Lifeworld' and 'System' to highlight a friction between embedded power structures represented, in this case, by EBM, and the lifeworld beliefs, values and experiences of citizens represented via the medium of qualitative research. I will highlight how 'the colonization' of the lifeworld by abstract sub-systems of authority and bureaucracy have tempered understandings and created a level of 'interference', in which the method of qualitative synthesis is currently contested.

The Lifeworld and the System.

Jürgen Habermas is a German philosopher and sociologist associated with the 'The Frankfurt School' of influential writers and thinkers who developed an interdisciplinary and reflective approach to understanding described as Critical Theory (Bohman, 2005). For much of the latter decades of the 21st century Habermas brought a critical perspective to the examination of questions of morality, rationality, politics, science and law. One of Habermas' most famous and influential texts, the Theory of Communicative Action (Habermas, 1986, 1987) discerns two interdependent and inter-related spheres, the Lifeworld and the System. Habermas conceives the Lifeworld as the everyday social horizon of people, rooted in shared understandings of culture, tradition and societal norms acquired

in places like the family, the church, community and school (Habermas, 1987). He places particular emphasis on the inter-relationships between people in the Lifeworld and their ability to communicate in a co-operative and mutually beneficial manner, a process which he describes as 'communicative action' (Habermas, 1986). Fundamental to the preservation of the Lifeworld is the ability of its citizens to reproduce shared understandings by engaging in actions based on a communicative rationality of truth, appropriateness and authenticity (Scambler, 2015). By way of comparison, Habermas perceives the System as a necessary adjunct of the Lifeworld, as a realm where communicative action is replaced by the instrumental rationality of strategic action and regulated by economic and bureaucratic forces (money and power) (Habermas,1987). In contrast to the more sinister and oppressive perceptions of the System conceptualized by Foucault, Weber and others, Habermas adopts a more neutral attitude given that, in his view, the System exists as a strategic entity to fulfil the mutually agreed administrative and transactional duties, associated with the Lifeworld (Scambler, 2015). Where Habermas does have a concern with the System is in complicated, modern societies where social integration and thus communicative action become more complex and fragmented. From Habermas' perspective modern society has created an imbalance between Lifeworld and the System such that sub-system components of economy, bureaucracy and technology and associated norms of efficiency and strategic action infiltrate everyday life, suppressing opportunities for communicative action (Abma et al., 2017). He refers to this dynamic as 'colonization' and views it, in negative terms, as a loss of meaning:-

"When stripped of their ideological veils, the imperatives of autonomous subsystems make their way into the lifeworld from the outside – like colonial masters coming into a tribal society – and force a process of assimilation upon it" (Habermas, 1987, p.355).

In a healthcare context various authors allude to Habermas' notion of colonization to highlight the increasing use of strategic actions (for example, the use of administrative, diagnostic and treatment procedures) to the detriment of communicative actions associated with the patient's Lifeworld

experience (Scambler, 2001; Fredriksen, 2003; Rich-Ruiz et al., 2014). Within a maternity context Scambler (1987) suggests that obstetricians were 'unwitting agents of colonization' when, in the 1970's, they started to advocate for increasingly technocratic, hospitalized births to facilitate System led imperatives rather than Lifeworld understandings. It is within this dynamic where systemized norms of rationality, apparent within the principles of EBM, compete with cultural, societal and personal understandings of healthcare emanating from the Lifeworld. When referring to the space where Lifeworld understandings meet systemized norms, Abma et al. (2017) describe 'an interference zone' in which *"logics (system and lifeworld) permanently strive for priority and lead to continuously changing context-bound formations"* (p.510). I suggest that many of the areas of contestation highlighted in this commentary take place in this interference zone, particularly those relating to the use of standardized tools and techniques derived from quantitative research in the area of qualitative synthesis. Sally Thorne's critique of recent developments in this field allude to the colonization of qualitative synthesis by a *'new species of product*' which seems to have *'taken over'* (2017) whilst Malterud (2019) suggests that, "*influential methodological values and ontological assumptions from the EBM tradition have permeated the entire range of research synthesis, including qualitative metasynthesis"* (p.10).

Habermas indicates that colonization by the System should be resisted and that key agencies of resistance emerge as social movements. I suggest that the views of Malterud, Thorne and others represent a form of scholarly communicative rationality or 'methodological resistance'. The struggle these authors allude to is simultaneously an attempt to maintain the integrity of qualitative synthesis as a distinct methodological approach and an act of resistance against the imposition of Systemized tools from a colonizing presence.

In a wider context Habermas' notion of resistance relies on social consensus rather than confrontation or revolution, albeit a consensus that can be at ease with a plurality as opposed to singular solutions to particular problems. He suggests that communicative actions based in the

context of the Lifeworld and including as many participants as possible, can re-establish meaning and contribute to 'decolonization' (Habermas, 1987). This understanding resonates closely with the ethos of qualitative synthesis which seeks to respectfully accommodate a plurality of opinions from a diverse range of settings. In the context of clinical guidelines, I suggest that the use of qualitative synthesis reflects the Lifeworld cultural traditions, societal beliefs and personal experiences of stakeholders pertaining to a particular phenomenon and represents a form of decolonization. However, as noted previously, this is happening in an interference zone where the tools and techniques appropriated from systemized authorities, notably the EBM movement, continue to serve as reminders of a colonizing presence. To address this persistent unease, I suggest that Habermas' notion of resistance be applied to the initial construction of guidelines such that Lifeworld understandings illuminated in the form of qualitative synthesis set the parameters of a guideline. In this way, the collective, communicative voice of as many stakeholders as possible determines the scope of a guideline utilizing an approach which seeks to convey Lifeworld meaning, rather than *de facto* meaning based on instrumental, System led imperatives. Such an approach would further enhance decolonization and represent a more consensual, person-centred trajectory.

In a political sense, critics of Habermas often focus on his 'idealized' depiction of decolonization, particularly the difficulty of achieving social consensus in complex, diverse societies in which System led imperatives hold sway (Shapiro, 1999; Hendriks, 2009). The notion that Habermas' theories are in some way idealized also feature in criticisms of his Lifeworld/System conception and the over-simplistic relationships between power structures in these two realms (Baxter, 1987; McCarthey, 1991). In part, Habermas agrees with these criticisms but portrays the 'idealized' concepts of his social theory within a more comprehensive and dynamic, democratic process which he describes as 'the unfinished project of modernity' (Habermas, 1997). Habermas contends that his social theory,

"should contribute to the interpretation of conflicts which arise as a result of the over-legalisation and bureaucratisation of areas of life, and it should do so with the intention of assisting those

struggling to resist this development to clarify for themselves the conflicts in which they are involved" (Habermas, 1986, p.29, as cited by Blaug, 1999)

In this regard I suggest that Habermas' theoretical discourse, particularly the Lifeworld/System dynamic and the associated concepts of colonization and decolonization, illuminates the areas of contestation pertaining to qualitative synthesis and guideline development. The application of System oriented techniques and procedures to Lifeworld understandings represents a subtle form of colonization and is being met with resistance. From a wider perspective, qualitative synthesis may not reflect Habermas' notion of social consensus, since any 'consensus' in qualitative synthesis is usually achieved by academic interpretations of primary research. However, it does optimise both stakeholder input and diversity of opinion and presents consensus in the form of synthesized findings (concepts or themes) through an interpretive lens. To this end qualitative synthesis arguably allays some of the 'idealistic' critiques of Habermas' theories by offering a practical solution to optimise stakeholder engagement.

In the final section of this commentary I will focus on maternity care guidelines that have been published by WHO since 2015, to examine claims that the incorporation of qualitative evidence renders global guidelines more 'person-centred', both in their content and in their application in practice. I will explore Carl Rogers original conception of person centredness to argue that these claims may be overstated and integrate Habermas' notion of decolonization to further develop an alternative approach. Finally, I will explore current applications of qualitative synthesis in clinical guidelines and look at recent developments in this rapidly evolving field.

Person-centred Guidelines

In addition to the widespread adoption of the person-centred care model in clinical settings there is increasing recognition that healthcare policy and guideline development should also incorporate

person-centred principles (van de Bovenkamp & Trappenberg, 2009; van Dulmen et al., 2015; WHO, 2015; Anjum, 2016; Wieringa et al., 2018). Recent guidelines in maternity care, including those we have contributed to, highlight their person-centred (or woman-centred) credentials in light of the contributions made by qualitative syntheses (WHO, 2016; WHO, 2018a). Indeed, the stated aim of the 'WHO recommendations on antenatal care for a positive pregnancy experience' is:-

"to provide a clear, evidence-based framework for ANC practices that empowers all pregnant women and adolescent girls to access the type of person-centred care that they want and need…." (WHO, 2016, p.2).

However, as noted above, the assimilation of highly descriptive, CERQual graded qualitative review findings into relevant sections of EtD frameworks is based on positivist principles and may be interpreted as an example of System oriented colonization. I suggest that such an approach isn't reflective of person-centredness and may be viewed as merely 'complementary' or 'supplementary' to the evidence generated from effectiveness reviews (Gould, 2010; Fearon et al., 2018). Since the use of qualitative synthesis in guideline development is a relatively new phenomenon there is no clear guidance on how to embody a person-centred approach and a deeper understanding of the original concept, as outlined by Carl Rogers, may be required.

Rogers work in the field of psychotherapy during the middle decades of the previous century brought him to the realization that his clients had, within themselves, all of the resources required to develop and 'self-actualize' and that his role, as a therapist, was to facilitate this transformation:-

"the individual has within him or herself vast resources for self-understanding, for altering the self-concept basic attitudes, and his or her self-directed behaviour - and that these resources can be tapped if only a definable climate of facilitative psychological attitudes can be provided" (Rogers, 1980, p.115).

This tendency towards 'self-actualization' was contrary to the prevailing Freudian understandings of the time whereby the patients (clients) capacity to improve their mental and emotional well-being was largely determined by the knowledge, skill and expertise of the therapist. Rogers' use of the term 'person centred' therefore refers to a fundamental concept that portrays the client as the expert and main protagonist in their own psychological and emotional development rather than a patient reliant on the superior wisdom of an authoritative figure (Rogers, 1990). For Rogers a 'climate of facilitative psychological attitudes' encompasses three core conditions, namely congruence (or authenticity), unconditional positive regard and empathy. By meeting these conditions, or more accurately, by adopting these attitudes, the space for genuine discourse and ultimately client self-empowerment is created (Rogers, 1980). Similarly, from a Habermasian perspective, the conditions for 'valid' communicative action are threefold and relate to truth, appropriateness and sincerity (Habermas, 1986). Thus, for both authors the conditions for effective dialogue and ultimately for emancipation (on an individual and societal level), require genuine, honest contributions from individuals untainted by professional façade or System generated hierarchies[3].

Based on these understandings I suggest that, within the current context of clinical guideline development, there is still a tendency to adhere to the Freudian notion of 'professional expertise' since the initial scope of guidelines, as well as topic selection, is largely determined by System oriented hierarchical panels of experts or Guideline Review Committees (GRCs) (WHO, 2015; NICE 2013). In this regard, I contend that the inclusion of descriptive findings from qualitative syntheses to inform the acceptability and feasibility criteria of EtD frameworks may be considered as supportive rather than informative and whilst stakeholder values, based on Lifeworld experiences

[3] An interesting precursor to both Rogers and Habermas was the earlier Frankfurt School member Erich Fromm. In *The Sane Society* (1956), Fromm posed the question in what ways would society have to be shaped to avoid both the twin threats of consumer capitalism and authoritarian statism, whether organised from the right or left. Arguably, this provided the platform for theories and practice of person-centredness and communicative action, embedded within a reformist approach to liberal democracy

are acknowledged, they largely relate to *a priori* interventions agreed by the GRC. For example, in a recent critique of a NICE guideline on the use of 'Opioids in Palliative Care' the authors draw attention to a predetermined guideline outcome that measured pain on a numerical scale (in accord with an instrumental, biomedical approach) and indicate that this was unlikely to be useful to patients who would be more interested on the impact of pain in performing their daily activities and maintaining relationships in the context of the Lifeworld (Fearon et al., 2018).

In theory, the findings from a qualitative synthesis exploring 'what matters' to patients and service users with regard to a particular disease, condition, or, in a maternity context, life event, could help to set the parameters of a guideline and determine the type of interventions to be explored along with relevant person-centred outcomes. Such an approach would not only acknowledge the contribution of the 'patient as expert', more accurately reflecting the Rogerian concept of person-centred, it would also accommodate Habermasian notions of decolonization via the reproduction and synthesis of Lifeworld understandings. Freed from the constraints of System dominated hierarchies and disentangled from the confinements of rigid, positivist, evaluative procedures the values, beliefs and experiences emerging from Lifeworld understandings could lead to genuine person-centred guidelines.

Although two of our three syntheses exploring the wants and needs of women in the areas of antenatal and intrapartum care (Downe, **Finlayson** et al., 2015; Downe **Finlayson** et al., 2018) were guided by these novel principles the findings weren't used to inform the initial scope of the guideline or relevant interventions. These parameters had already been established by professional experts (the GRC) and were largely bio-medical in scope and framed around risk, pathology and clinical interventions (WHO, 2016; 2018a). The 'positive experience' headlines give the impression of person-centredness without the underlying components of a positive experience (see Box 2) playing a significant role in the scope and development of the guideline questions. I contend that to be genuinely reflective of a person-centred approach, the patient voice (in the form of a qualitative

synthesis) should be represented at the earliest stage of guideline development to establish parameters rather than a supplementary sub-text. It is therefore interesting and encouraging to note that our most recent publication relating to women's wants and needs in the post-natal period (**Finlayson,** Crossland et al., 2020), is currently being used to inform the initial scope of the forthcoming WHO guidelines in this area.

Moving forward there does appear to be an impetus to endorse a more person-centred approach (Armstrong et al., 2018; Roddis et al., 2019). The multi-agency supported G-I-N organization (Guidelines International Network), whose aim is to strengthen and support collaboration within guideline development, have developed a toolkit for guideline developers which not only advocates patient (public) engagement in defining the initial scope and topic selection, it also endorses the use of qualitative synthesis as a method for doing so (G-I-N PUBLIC Toolkit, 2015).

However, more recent initiatives in guideline development being pioneered by the WHO include the production of so called, 'Living Guidelines', whereby guidelines are prioritized and updated on the basis of new, potentially significant evidence, shortly after the data is published rather than every 5 years or so (Vogel et al., 2019). Whilst this approach addresses one of the criticisms often levelled at clinical guidelines, that they go out-of-date relatively quickly (Shojania et al., 2007; Martinez Garcia et al., 2014), the decision on whether to prioritize a guideline is largely based on incoming evidence from RCTs (Uhlig et al., 2016; Vogel et al., 2019). This development once again shifts the emphasis away from a person-centred approach and back to a Systems oriented, professionally led procedure based on expert judgement. Although there is an argument that qualitative syntheses may be concept saturated and therefore not amenable to regular updates, France et al. (2016) indicate there may be potential. The authors propose that qualitative syntheses could be updated according to the same or similar standards currently applied to the Living Guidelines approach including:-

1. Time sensitivity – if the previous synthesis is relatively old and recent advances in practice or treatment have changed substantively then an update may be required.

2. New publications – if there have been a substantial number of new studies on the same topic then an update may be required.
3. Quality – if the quality of the previous synthesis did not meet current standards then an update may be required.
4. New patient populations or interventions or healthcare contexts – if new and original phenomena are identified then an update, and probably a revised review question, may be required.

Based on a rationale comprising 2 and 4 (above) the same authors updated an existing qualitative synthesis on 'patient's experiences of head and neck cancer' with findings from several new qualitative studies by using an adaptation of Noblit and Hare's (1988) meta-ethnographic technique (France et al., 2016). Their findings indicate that it is not only possible to update qualitative syntheses but also to use the same or similar indicators as those used in quantitative reviews to trigger a Living Guideline update. Existing guidelines could therefore utilize either quantitative or qualitative indicators (or both) to initiate Living Guideline updates.

In a similar vein, as the number of published qualitative syntheses continues to increase there may also be scope to 'synthesize syntheses' in instances where the phenomena of interest is the same. Toye et al. (2017) synthesized the findings from 11 different qualitative syntheses exploring 'patient experiences of living with non-malignant chronic pain', using an adaptation of meta-ethnography, and termed the resultant output 'a mega-ethnography'. This methodology is a very recent development and although there is scope for refinement, I foresee further contestation amongst academics working in this field largely framed around the notion of 'an abstraction too far'.

In summary, by incorporating qualitative data into clinical guidelines there is a move towards framing the resultant recommendations as 'person-centred'. Recent guidelines in maternity care reflect this development. However, closer inspection of Rogers original conception of person-centredness suggests that behind the rhetoric these guidelines retain a hierarchical, Systems

oriented approach. By utilizing qualitative synthesis at the beginning of guideline development to find out what matters to people in relation to a specific, healthcare phenomena a more person-centred approach can be achieved.

Conclusion

The use of qualitative synthesis in the development of clinical guidelines has propelled qualitative research into the limelight. From a position of relative inferiority, the findings from qualitative studies, presented in the form of synthesis, are now regarded as evidence by influential and powerful organizations affiliated with the EBM movement. Indeed, the preferred Cochrane term for this new endeavour is Qualitative *Evidence* Synthesis (QES), a clear endorsement of the credibility of the approach in generating useable knowledge. Based on these assumptions there is an argument that the established hierarchy of evidence may be better represented as a 'continuum of evidence' with positivist approaches like meta-analysis at one end and interpretivist approaches like meta-ethnography at the other. Such a model would allow guideline panels and policy makers to draw on a broad range of evidence to support specific healthcare decisions without being led by a perceived bias towards effectiveness reviews. However, the emergence of qualitative synthesis into an evidence base traditionally dominated by quantitative studies and spearheaded by data from RCTs has created conflict and epistemological friction. As well as philosophical debates concerning validity and integrity, persistent tensions relate to the methodological characteristics of the approach and, notably, their application in the development of clinical guidelines.

Against this background, it is perhaps unfortunate that meta-ethnography has been adopted by academics and researchers as the favoured approach to the synthesis of qualitative studies. Out of all possible synthesis techniques it is, arguably, the most dated, most interpretive and least penetrable to researchers from non-qualitative disciplines. When Noblit and Hare (1988) first introduced meta-ethnography more than 30 years ago they emphasized interpretation over

aggregation and outlined their approach using very small numbers of carefully selected, unevaluated, ethnographic studies in the field of education. At that time, they could not have anticipated the explosion of syntheses purporting to use meta-ethnography, incorporating dozens of qualitative studies (of all types) emanating from complex, systematic searches of databases and utilizing detailed assessment tools to evaluate study quality and confidence in findings. As this commentary illustrates these 'new species' of synthesis emphasize the procedural components of the endeavour as *de facto* indicators of quality, as if the procedures themselves provide sufficient justification to compete in the evidence hierarchy. An exhaustive and complex search strategy aimed at retrieving the maximum number of studies doesn't make the subsequent synthesis more 'valid', rather it enhances the prospect of an aggregative synthesis instead of an interpretive one; the use of a quality appraisal tool doesn't necessarily guarantee the quality of the synthesis, rather it reinforces the procedural 'correctness' of the included studies instead of the richness of the findings; ultimately, confidence in the findings from a qualitative synthesis, especially a meta-ethnography, should not depend on positivist adjudications of knowledge (embodied in items like the CERQual tool) but rather on their integrity to the original methodology. Despite Noblit and Hare's (1988) expectation (and hope) that qualitative synthesis, specifically, meta-ethnography, would evolve they were quite clear that the interpretive intent should be paramount:-

"The more formal qualitative researchers (e.g. Miles and Huberman, 1984) see the issue of comparing studies as one of explicitness about the processes we use to analyse data. We tend to agree with Marshall's (1985) assessment that this is the "bureaucratization" of data analysis. The meta-ethnographic approach we develop here takes a different tack: we focus on constructing interpretations, not analyses" (p.11).

The recent publication of the eMERGe reporting guidance for meta-ethnography (France et al, 2019), which feature George Noblit as a co-author, remind prospective synthesists of the original interpretive nature of the approach. Whilst the reporting guidance itself may, ironically, be

perceived as prescriptive, the intention is to maintain the integrity of the approach in the face of increasing threats posed by colonized by-products.

Based on these premises I maintain that in the two earlier qualitative syntheses (Downe, **Finlayson** et al., 2009; **Finlayson** & Downe., 2013) contributing to this commentary we largely followed the interpretive principles of meta-ethnography to generate novel theoretical concepts around antenatal care access. Indeed, the theoretical knowledge presented in the latter synthesis was enough to pique the interest of researchers at the WHO and Cochrane Effective Practice and Organization of Care (EPOC) group. However, in the subsequent synthesis used to inform the WHO antenatal guidelines (Downe, **Finlayson** et al., 2019) we were encouraged to adopt the procedure-laden approach advocated by Cochrane to construct a Qualitative Evidence Synthesis (QES). In the 'interference zone' where guideline development is currently contested QES appears to represent a methodological medium in which EBM can incorporate the findings from qualitative studies and qualitative research can penetrate the previously inaccessible boundaries of EBM. However, this apparent compromise conceals a hegemonic power structure that prioritizes objective knowledge over inter-subjective understanding. Seen from a Habermasian perspective, QES represents a colonized form of synthesis, with limited interpretive intent, designed to satisfy instrumental, Systemized notions of evidence.

According to these assumptions this commentary offers no further guidance on the 'best' method of synthesis or the most appropriate synthesis technique in the development of clinical guidelines. Ultimately, the choice of which synthesis technique to use may be determined by the epistemological stance of the review team and their own familiarity with a particular approach. So long as this position is made clear at the outset and the appropriate methodology is followed, the credibility of the approach should be implicit. However, as this commentary illustrates, where there is a disconnect between the epistemological stance of the review team and the favoured method of synthesis, particularly where this remains concealed, it can give rise to discord. Given the

epistemological roots of QES, with its procedural emphasis on the aggregation of positivist knowledge, it seems, at best, misguided and, at worst, ignorant, that such an approach would recommend interpretive approaches to synthesis over aggregative techniques.

Moreover, there is, arguably, a naivety on the part of healthcare institutions in making the assumption that guidelines automatically reflect a person-centred approach simply by assimilating the findings from a qualitative synthesis. In this regard guideline developers risk making the same mistake as healthcare practitioners in assuming that by adopting certain behaviours (listening to patients, encouraging shared decision-making) they are somehow practicing person-centred care (Ekman et al., 2011; Afulani et al., 2019). In clinical practice the patient centred approach requires a fundamental shift in thinking away from the Freudian notion of 'professional as expert' towards the Rogerian concept of 'patient as expert', into a space that Yelovich (2016) appropriately describes as 'the meeting of experts'. Similarly, for guideline developers an authentic person-centred approach requires a move away from professionally led, system focused frameworks to patient informed, Lifeworld oriented syntheses. Our two qualitative syntheses (framed as systematic reviews) exploring 'what mattes to women' during antenatal and intrapartum care (Downe, **Finlayson** et al., 2015; Downe, **Finlayson** et al., 2016) gave an insight into what could be achieved if the findings from such reviews were used in a person-centred manner, to set the scope of a guideline. Our most recent paper outlining 'what matters to women during the post-natal period' (**Finlayson**, Crossland, et al., 2020) and more confidently labelled as a meta-synthesis, sets the parameters for a more authentic, person-centred guideline. By adopting this strategy, the Lifeworld experiences, values and beliefs of patients can be used to determine which interventions should be reviewed and/or the nature of potential future interventions. Thus, qualitative synthesis acts as a medium for patient representation accommodating a wide range of perspectives from different contexts in a way that would be impossible under the traditional patient advocacy approach. From a Habermasian perspective this process of 'decolonization' enhances Lifeworld meaning in clinical guidelines and contributes to a rebalancing of the Lifeworld/System dynamic.

In this commentary I have explored some of the areas of philosophical and methodological unease in the field of qualitative synthesis. I have drawn particular attention to the use of standardized tools and techniques appropriated from positivist understandings and applied to what is, fundamentally, an interpretive pursuit. By employing some of Jürgen Habermas' conceptions of Lifeworld/System and colonization/decolonization I have provided an original way to engage with the subject matter and addressed some of the key issues from a theoretical perspective. I have used these understandings to further advance a novel approach to guideline development that utilizes Habermas' notion of decolonization (via social consensus) and Rogers' model of person-centredness to enhance and empower the patient voice. In so doing, I have incorporated the concept of the 'patient as expert' and shown that beyond the rhetoric, person-centred clinical guidelines are both desirable and achievable.

Original contribution to this area of research

As this commentary illustrates I have been involved in this area of research for more than 10 years, initially as a naïve research assistant excited by the possibility of using qualitative synthesis to influence healthcare policy and now as a more experienced research associate actually using the method to influence clinical guidelines at the highest level. I feel both privileged and humbled to be one of the first researchers approached by the WHO to act as a technical adviser on qualitative synthesis and am proud of the contributions I have made to several maternity care guidelines. Through my work with the WHO I have helped to shape some of the methodological advances in this area and the recent proliferation of qualitative syntheses, exploring many aspects of healthcare, arguably reflects the growing acceptability of these 'WHO endorsed' endeavours. In particular, the three 'what women want' syntheses, encompassing all three phases of maternity care, added a new dimension to the framing of the clinical guidelines and became the centre-point of the published recommendations, earning plaudits from both the General Director of the WHO and the Secretary

General of the United Nations (UN). My involvement with the WHO is ongoing and evolving and the recent publication of the 'what women want during the post-natal period' study promises to fulfil some of the person-centred potential in guideline development, as highlighted in this synopsis.

In addition to the papers included in this commentary, I have also co-authored a series of three articles explaining how the findings from qualitative evidence synthesis can be used to inform clinical guidelines – the first methodological papers to do so (Downe, et al. 2019; Glenton, et al. 2019; Lewin, et al. 2019). My hope is that these papers will encourage other researchers to engage with this fascinating area of research and generate further understandings relating to the application of qualitative research into policy and practice.

Going forward, I remain committed to this area of research and, in addition to wider dissemination of my published works through teaching engagements and conference attendance, I hope to develop and refine qualitative synthesis techniques in the context of guideline development. With this in mind I have recently become involved with the 'Living Guidelines' group at the WHO and am keen to develop strategies to advance this approach utilizing qualitative methodologies. I was the lead author on one of the first publications to emerge from the WHO 'Living Guidelines' strategy – a qualitative synthesis exploring the views of women and healthcare providers around the prevention of Post-partum haemorrhage (PPH) (Finlayson et al, 2019). Evidence from this synthesis was used to inform the updated 'WHO recommendations: Uterotonics for the prevention of postpartum haemorrhage' (WHO, 2018), one of the first Living Guideline updates to be published by the WHO.

Finally, I hope to use some of the theoretical, philosophical and personal insights from this commentary to further illuminate the relationship between qualitative synthesis and the generation of evidence. The application of Habermas' concept of colonization to this area of research has deepened my understanding not only of the subject matter, but also my own (researcher) role as a medium or 'conduit' between Lifeworld understandings and System oriented norms. The publication

` of a subsequent article highlighting this perspective would, I believe, lend additional weight

to the significance of qualitative synthesis as a method and further enhance the impact of voices from the Lifeworld.

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